S/N 09/655,074 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

NAKA ET AL.

Examiner:

L. ALEXANDER

Serial No .:

09/655,074

Group Art Unit:

1743

Filed:

JUL 1 9 2004

SEPTEMBER 5, 2000

Docket No.:

10873.164USC2

Title:

DEVICE AND METHOD FOR ANALYZING A SAMPLE

CERTIFICATE UNDER 37 CFR 1.10

'Express Mail' mailing label number: EV408489299US Date of Deposit: July 19, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service Express Mail Post Office To Addressee' service under 37 CFR 1.10 on the date indigated above and is addressed to Mail Stop Appeal Brief-Patents, the Commissioner for Patents, Alexandria, VA 2313-1400

Name

APPELLANTS' BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

23552

PATENT TRADEMARK OFFICE

Dear Sir:

This Brief is submitted pursuant to the Notice of Appeal filed on March 19, 2004.

1. Real Party in Interest

This application is assigned to ARKRAY, Inc. of Kyoto, Japan.

2. Related Appeals and Interferences

Appellants, their legal representative and the assignee are unaware of any pending appeals or interference that would directly affect, be directly affected by or have a bearing on the decision in the present appeal.

07/23/2004 HALI11

00000012 09655074

01 FC:1402

330.00 OP

3. Status of Claims

Claims 7, 9-18, 28-33, 38-44 and 46-76 are pending in the application. Claims 1-6, 8, 19-27, 34-37 and 45 have been canceled during prosecution. Claims 7, 10, 11, 18, 32, 33, 54, 55, 65 and 72 are considered objectionable as depending on a rejected claim but are not subjected to any rejections. Claims 9, 12-17, 28-31, 38-44, 46-53, 56-64, 66-71 and 73-76 are the subject of this appeal. The pending claims are reproduced in the appendix to this Brief.

4. Status of Amendments

No Amendment was filed in response to the final Office Action dated October 21, 2003.

5. Summary of Invention

As discussed on page 1 of the specification, the present invention is directed to a device for analyzing samples, and is useful in the field of analytical chemistry. For example, the device can be used for analyzing various medical fluids. The device has dimensions that permit it to be manipulated by hand. As such, the device of the present invention is useful for analyzing samples in clinical tests or the like.

Referring to Figs. 1A and 1B, as discussed at pages 22-26 of the specification, one embodiment of the device of the present invention includes a main body or base member 5b, which is closed by a flexible cover 5a. A drawing channel 2 is defined in the main body, and an analytical section 3 is formed in the drawing channel. An opening 4 is provided at the end of the drawing channel, through which a sample to be analyzed can be introduced to the device. A suction pressure generator may be provided in the main body, and in the case of Figs. 1A-B, this takes the form of a chamber 1 provided in the main body. Portion 2a of the drawing channel connects the analytical section 3 with the outside, and portion 2b of the drawing channel connects the analytical section 3 with the suction pressure generator. In use, if the flexible cover over the chamber 1 is depressed and then released, a reduced pressure is created in the chamber 1. This creates a suction that can be used to draw a sample through the drawing channel and into the analytical

section. Any reaction of the sample with a reagent disposed in the analytical section then can be evaluated.

As can be seen in Figs. 2-21, the device of the present invention is quite versatile, and is capable of being modified with a number of different features. For example, multiple drawing channels and analytical sections can be provided (Fig. 2, pages 26-29). A bypass channel 6 can be provided in the main body (Fig. 3, pages 29-31). By controlling the fluid flow rate in different portions of the drawing channel and/or the drawing channel, it is possible to ensure the delivery of a desired amount of sample to the analytical section. As seen in Fig. 15 (pages 57-60), multiple chambers can be formed in the drawing channel, for example to provide positions 32a and 32b for different reagents that react with a sample before it is delivered to the analytical section 31. In this embodiment, a sample pooling portion 9 is provided near the end of the drawing channel.

6. Issues

The following issues are raised in the final rejection:

- 1. Whether claims 50, 69-71, 74 and 76 are anticipated by US 3,620,676 (Davis);
- 2. Whether claims 50, 69-71, 74 and 76 are anticipated US 4,806,313 (Ebersole);
- 3. Whether claims 51-53, 60-64 and 66-68 are obvious over Davis or Ebersole; and
- 4. Whether claims 9, 12-17, 28-31, 38-44, 46-49, 56-59, 73 and 75 are rendered obvious by Ebersole or Davis in view US 4,859,421 (Apicella).

Appellants suggest that the fourth issue can be considered as two separate issues: (A) Claims 9, 12-17, 28-31, 38-44, 46-49, 73 and 75 (i.e. independent claim 28 and its dependent claims) and (B) claims 56-59 (which depend from independent claim 50).

Independent claim 28 and dependent claims 46-49 and 56-59 recite particular dimensions for the device. Page 4 of the March 18, 2003 Office Action (paper 15), referenced at page 2 of the October 21, 2003 final rejection, cites Apicella as suggesting dimensions within the ranges required by claims 28, 46-49 and 56-59. This appears to be the sole purpose for which Apicella is cited. For purposes of this appeal only, Appellants

are not disputing the rejection's interpretation of Apicella for the dimensions, nor the suitability of Apicella for combination with Davis. Therefore, the Argument below focuses on the relevance of Davis and Ebersole to the remaining aspects of the claims.

7. Grouping of Claims

Claims 13, 29-31, 39-40, 42-44, 70, 73, 74, 75 and 76 support additional arguments for patentability, as discussed below. Claims 61 and 66, which are included in the rejection for obviousness over Davis or Ebersole, are considered to stand or fall with independent claim 50 for the purposes of this appeal only. Again for the purposes of this appeal only, the remaining claims are considered to stand or fall together within the individual rejections, it being noted that several of the claims in the third issue are directed to different aspects that are argued individually in the discussion of this rejection in section 8C. In this regard, claims 51-53, 62, 63, 67 and 68 stand or fall together for the purposes of this appeal, and claim 64 supports an additional argument.

8. Argument

A. Claims 50, 61, 66, 69 and 71 Are Not Anticipated By US 3,620,676 (Davis)

Claim 50 requires, inter alia, a main body, a suction pressure generator that comprises a chamber formed in the main body, and a flexible cover on the main body. Movement of the flexible cover creates changes in pressure in the chamber of the suction pressure generator.

The Davis device includes a planar backing sheet 11 and an embossed front member 12, which is formed of a synthetic plastic composition such as polyvinyl chloride. The front sheet is formed to define a cavity that has a half tubular lower portion 13 and a compressible half bulb upper portion 14 connected to the lower portion.

Davis cannot be interpreted to meet the requirements of claim 50. If the backing sheet 11 is considered as the main body of claim 50, Davis has no suction pressure generator comprising a chamber "formed in the main body" as required by claim 50. The planar sheet 11 is completely unsuitable for formation of a chamber. If the front sheet 12 is considered as the main body of claim 50 with the half bulb structure acting as the suction pressure generator, Davis has no flexible cover whose movement causes changes

in pressure in the chamber of the main body. Davis nowhere discusses that the backing sheet should be moved to change pressure in the half bulb structure. Instead, col. 1, lines 26-27 specifically teach that the front sheet is the compressible member.

Moreover, in Davis, an indicator stripe extends the entire length of the hollow portion of the device. Nothing in the reference distinguishes between a drawing channel and an analytical section. Any analytical section in the Davis device thus does not communicate with the exterior of the device through a drawing channel as required by claim 50.

Therefore, Davis does not meet all of the requirements of claim 50 and claims 69 and 71 that depend from claim 50. Claims 61 and 66, which are included in the rejection for obviousness over Davis or Ebersole, are allowable for at least the same reasons as claim 50.

B. Claims 50, 61, 66, 69 and 71 Are Not Anticipated by US 4,806,313 (Ebersole)

Claim 50 requires the main body to be dimensioned to be manipulated by hand. Ebersole fails to anticipate this aspect of claim 50. Ebersole is directed to a rapid assay multiport flow through processor. Fig. 1 shows that the Ebersole device is a relatively large and complex apparatus that includes a control unit, vacuum source, reagent and wash sources, etc. The Ebersole apparatus uses a pump as a suction generator. Such an apparatus does not have a main body dimensioned to be manipulated by hand as required by claim 50. The Ebersole apparatus would not be useful in the same fields as the present invention, e.g. for carrying out clinical tests and the like. Therefore, Ebersole relates to a completely different technical field than the present invention, and neither discloses nor suggests the invention of claim 50.

The rejection seems to assume that the individual receptacles (pipettes 36) illustrated in Fig. 2 of Ebersole can be interpreted as the device for collecting samples for analysis of claim 50. Even accepting this interpretation of the reference as correct, Ebersole's individual receptacles fail to meet the requirements of claim 50.

As discussed above in A, claim 50 requires a main body, a suction pressure generator that comprises a chamber formed in the main body, and a flexible cover on the

main body. Movement of the flexible cover creates changes in pressure in the chamber of the suction pressure generator. Claim 50 also requires a drawing channel formed in the main body. An analytical section is formed in the drawing channel.

Initially, Appellants question the general applicability of Ebersole to claim 50. The rejection's analysis of the pipettes as including a main body and a flexible cover is a strained and hindsight interpretation at best. In any event, even if the general applicability of the Ebersole pipettes is accepted, the pipettes still do not meet the limitations required by claim 50.

The receptacles of Ebersole are in the form of a pipette having tubular portion 40 and a flexible bulbous portion 38. As discussed at col. 9, line 11, the pipettes have a one-piece construction. There is no basis for arbitrarily dividing these one-piece pipettes into the main body and flexible cover of claim 50 as required to support the rejection.

Moreover, no matter how the pipettes are divided, they cannot be interpreted to provide both (a) a main body with (1) suction pressure generator comprising a chamber and (2) drawing channel and analytical section formed in the main body and (b) a flexible cover on the main body whose movement creates pressure differences in the chamber. The flexible bulb is the only suction generating structure for the pipettes of Ebersole.

Therefore, if the "main body" of the pipette is defined to meet the noted requirements 1 and 2 of the main body of claim 50, the flexible bulb has to be part of the main body and there is no structure remaining to qualify as the flexible cover. If the main body of the pipette is defined as including only the tubular portion 40 so that the flexible bulb could be argued to qualify as the flexible cover, there is no suction generator comprising a chamber formed in the main body.

Therefore, Ebersole does not meet all of the requirements of claim 50 and claims 69 and 71 that depend from claim 50. Claims 61 and 66, which are included in the rejection for obviousness over Davis or Ebersole, are allowable for at least the same reasons as claim 50.

C. Claims 51-53, 60, 62-64 and 67-68 Are Not Suggested By Davis or Ebersole

Claim 51 requires a bypass channel formed in the main body and communicating with the suction pressure generator. The bypass channel branches from the drawing channel at a position between the analytical section and the opening from the main body. Claims 52 and 53 require that the drawing channel branch into a plurality of drawing channel members. Claims 62 and 63 require a bypass channel. Claims 67 and 68 require a liquid pooling portion between the opening of the main body and drawing channel, and an air vent passage. Nothing in the Davis or Ebersole disclosures remotely suggests that such a structure should be provided in the Davis indicator or the Ebersole pipette. Nothing in the present record indicates how such structures even could be provided in the devices of Davis and Ebersole; neither of the reference devices is configured to accept such branched structures.

Claim 64 requires a structure in which positive pressure can return a sample withdrawn from the analytical section to the analytical section. Neither Davis nor Ebersole suggests such a feature. Neither reference provides a distinct "analytical section", and therefore there is no reason to modify the references to be able to return a sample to the analytical section with positive pressure.

Claim 60 depends from claim 54, which has not been subjected to a rejection. Therefore, claim 60 is allowable for at least the same reasons that claim 54 is considered allowable. Appellants are not conceding that claim 60 does not support additional arguments for patentability.

D. Claims 70, 74 and 76 Are Further Removed From Davis and Ebersole

Claim 70 depends from claim 50 and requires the presence of independent reagent positioning section, reagent reaction section and analytical section in the drawing channel. Neither Davis nor Ebersole includes anything like these features.

Claim 74 depends from claim 50 and requires a concave portion with a cylindrical inner shape formed in the main body as the chamber of the suction pressure generator. Neither Davis nor Ebersole discloses such a feature. As discussed above in A, the planar backing sheet 11 of Davis must be considered as the "main body" of the reference if the

reference is to have a flexible cover as required by claim 50. This structure is manifestly unsuitable for a concave portion with cylindrical inner shape as required by claim 74. The pipettes of Ebersole are equally unsuitable for such a structure.

Claim 76 depends from claim 50 and requires the analytical section to be wider than the drawing channel, and requires that the drawing channel extend from the analytical section to the suction generator. Neither Davis nor Ebersole suggests such a feature. Davis includes a single stripe of indicator material 16 that is provided on the backing sheet 11 extends for the full length of the half-tubular and half-bulb shaped portions of the front sheet. In Davis there is no particular analytical section that is distinct from any "drawing channel" or "suction pressure generator" that can be found in the Davis device. Therefore, there is no reason to conclude that Davis has an analytical section that is wider than the drawing channel, as required by claim 76, nor that Davis provides a drawing channel between the analytical section and the suction pressure generator. The pipettes 36 of Ebersole seem to be illustrated as having a tapered end. The rejection contends that the tapered end can be considered the drawing channel as required by claim 50 and claim 76. Even if it is accepted that the tapered end generically could be considered a drawing channel, with the remainder of the tubular portion being an "analytical section", a point that is not being conceded here, Ebersole still fails to provide any such "drawing channel between the tubular portion 40 and the flexible bulb.

Therefore, each of claims 70, 74 and 76 is further removed from the references.

E. Claims 9, 12, 14-17, 28, 39, 41 and 46-49 Are Not Suggested by Davis, Ebersole and Apicella

Independent claim 28 requires a main body dimensioned to be manipulated by hand, a suction pressure generator, a drawing channel formed in the main body, and an analytical section formed in the drawing channel. This structure is not suggested by Davis or Ebersole. The discussion of the content of the Davis and Ebersole references in sections A and B above is applicable here, and is not being repeated. As mentioned in Section 6, Appellants are not contesting the relevance of Apicella for the specific dimensions recited in claim 28 for the purposes of this appeal alone.

In Davis, an indicator stripe extends the entire length of the hollow portion of the device. Nothing in the reference distinguishes between a drawing channel and an analytical section. Any analytical section in the Davis device thus does not communicate with the exterior of the device through a drawing channel as required by claim 28.

Ebersole is directed to a rapid assay multiport flow through processor. Fig. 1 shows that the Ebersole device is a relatively large and complex apparatus that includes a control unit, vacuum source, reagent and wash sources, etc. Such an apparatus does not have a main body dimensioned to be manipulated by hand as required by claim 28. The Ebersole apparatus is from a completely difference technical field than the invention of claim 28, and would not be useful for the same purposes as the invention of claim 28, e.g. for clinical testing.

In addition, Ebersole discloses that the receptacle 36 is a one piece pipette. Even if the portion 40 properly is considered as a main body, the structure is simply a tube. There is no drawing channel formed in this main body as required by claim 28, nor is there an analytical section formed in the drawing channel as required by claim 28.

Therefore, independent claim 28 and its dependent claims 9, 12, 14-17, 39, 41 and 46-49 are not suggested by the combination of Davis or Ebersole with Apicella.

F. Claims 13, 29-31, 38, 40, 42-44, 73 and 75 Are Further Removed From the References

Claims 29-31 include features like those of claims 51-53 discussed in Section C above. Claims 38 depends from claim 32, which was not subjected to a rejection, and is allowable for at least the same reasons. Appellants are not conceding that claim 38 does not support additional arguments for patentability. Claims 42-44 include features like those of claims 62-64 discussed in Section C above. Claims 73 and 75 include features like those of claims 74 and 76 discussed in Section D above. Therefore, these claims support additional arguments for patentability previously set forth in Sections C and D, which will not be repeated.

Claim 40 requires that the suction pressure generator include a chamber formed in the main body in communication with the drawing channel through its dependence on claim 39, and further requires a flexible cover on the main body, with changes in pressure in the chamber being created by movement of the flexible cover. Therefore, claim 40 includes the features of claim 50 discussed above, with additional limitations on the dimensions of the device being included through the ultimate dependence of claim 40 on claim 28. Therefore, the arguments presented above for claim 50 are applicable for claim 40.

G. Claims 56-59 Are Allowable With Claim 50

Claims 56-59 are included in the rejection for obviousness over Davis or Ebersole in view of Apicella. As noted above in section 6, for purposes of this appeal only, Appellants are not disputing the rejection's interpretation of Apicella for the features of claims 56-59, or the suitability of this teaching of Apicella for combination with Davis. However, claims 56-59 are allowable for at least the reasons discussed above for their independent claim 50.

Conclusion

The rejections of claims 9, 12-17, 28-31, 38-44, 46-53, 56-64, 66-71 and 73-76 are untenable and should be reversed.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, Minnesota 55402-0903 (612) 332-5300

Date: 1,2004

23552

Douglas P. Mueller Reg. No. 30,300

DPM

APPENDIX 1

THE CLAIMS ON APPEAL (as finally amended)

- 7. A device as claimed in claim 32, wherein a plurality of analytical sections are formed in the drawing channel, and the stopper is provided in the drawing channel between said suction pressure generator and the analytical section closest to the suction pressure generator.
- 9. A device as claimed in claim 28, wherein the opening has a shape enlarging toward the end.
- 10. A device as claimed in claim 28, wherein a liquid pooling portion is formed between the opening and the drawing channel, and an air vent passage branches from a portion of the drawing channel between the liquid pooling portion and the analytical section, the end of the air vent passage opening to the outside.
- 11. A device as claimed in claim 10, wherein the liquid flow resistance in the air vent passage is larger than the liquid flow resistance in the liquid pooling portion.
- 12. A device as claimed in claim 28, wherein the analytical section formed in the drawing channel serves as a reagent positioning section and a reagent reaction section.
- 13. A device as claimed in claim 28, wherein a reagent positioning section, a reagent reaction section and an analytical section are provided independently in certain positions in the drawing channel.
- 14. A device as claimed in claim 13, wherein a plurality of reagent positioning sections are provided in certain positions in the drawing channel.
- 15. A device as claimed in claim 28, wherein the suction pressure generator is a suction pressure generating chamber capable of changing its volume.

- 16. A device as claimed in claim 15, wherein a vent is formed in the suction pressure generating chamber.
- 17. A device as claimed in claim 28, wherein the suction pressure generator is a suction pressure generating tube.
- 18. A device as claimed in claim 28, wherein a pair of electrodes comprising a working electrode and a counter electrode is provided in at least one analytical section.
- 28. A device for collecting a sample for analysis, comprising:

a main body dimensioned to manipulated by hand, the device having at least one dimension selected from the group consisting of a length of 15-100 mm, a width of 20-50 mm, a width of 5-20 mm and a thickness of 1-5 mm;

a suction pressure generator;

a drawing channel formed in the main body in communication with the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator; and

an analytical section formed in said drawing channel between the suction generator and the opening, the analytical section communicating directly with the exterior of the device through the drawing channel,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

29. A device as claimed in claim 28, further comprising a bypass channel formed in the main body and branching from the drawing channel at a position between the analytical section and the opening and in communication with the suction pressure generator, wherein the relationship between a liquid flow resistance (X) in a first portion of the drawing channel between said analytical section and said suction pressure

generator, a liquid flow resistance (Y) in the bypass channel and a liquid flow resistance (Z) in a second portion of the drawing channel between the position at which said bypass channel branches and said analytical section satisfies the inequality (X) > (Y) > (Z).

- 30. A device as claimed in claim 28, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an analytical section and being in communication with the suction pressure generator.
- 31. A device as claimed in claim 29, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an analytical section and being in communication with the suction pressure generator, the bypass channel branching from the drawing channel at a position between the division point and the opening.
- 32. A device as claimed in claim 28, wherein a gas-permeable and liquid-impermeable stopper is provided in the drawing channel between the suction pressure generator and the analytical section.
- 33. A device as claimed in claim 32, wherein the stopper is made from a hydrophobic porous material.
- 38. A device as claimed in claim 32 wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator.
- 39. A device as claimed in claim 28, wherein the suction pressure generator comprises a chamber formed in the main body in communication with the drawing channel.

- 40. A device as claimed in claim 39, further comprising a flexible cover on the main body, whereby changes in pressure in the chamber of the suction pressure generator are created by movement of the flexible cover.
- 41. A device as claimed in claim 28, wherein the device is designed to be discarded after a single use.
- 42. A device as claimed in claim 28, further comprising a bypass channel formed in the main body and branching from the drawing channel at a position between the analytical section and the opening and in communication with the suction pressure generator.
- 43. A device as claimed in claim 42, wherein a liquid flow resistance in a first portion of the drawing channel between said analytical section and said suction pressure generator is greater than a liquid flow resistance in the bypass channel and a liquid flow resistance in a second portion of the drawing channel between said analytical section and a position at which said bypass channel branches.
- 44. A device as claimed in claim 28, wherein a positive pressure can be generated to return a sample withdrawn from the analytical section to the analytical section.
- 46. A device as claimed in claim 28, wherein the length is 15 to 100 mm.
- 47. A device as claimed in claim 28, wherein the width is 20 to 50 mm.
- 48. A device as claimed in claim 28, wherein the width is 5 to 20 mm.
- 49. A device as claimed in claim 28, wherein the thickness is 1 to 5 mm.
- 50. A device for collecting a sample for analysis, comprising: a main body dimensioned to manipulated by hand;

a suction pressure generator comprising a chamber formed in the main body; a drawing channel formed in the main body in communication with the chamber of the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator,

a flexible cover on the main body, whereby changes in pressure in the chamber of the suction pressure generator are created by movement of the flexible cover, and

an analytical section formed in said drawing channel between the suction generator and the opening, the analytical section communicating directly with the exterior of the device through the drawing channel,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

- 51. A device as claimed in claim 50, further comprising a bypass channel formed in the main body and branching from the drawing channel at a position between the analytical section and the opening and in communication with the suction pressure generator, wherein the relationship between a liquid flow resistance (X) in a first portion of the drawing channel between said analytical section and said suction pressure generator, a liquid flow resistance (Y) in the bypass channel and a liquid flow resistance (Z) in a second portion of the drawing channel between the position at which said bypass channel branches and said analytical section satisfies the inequality (X) > (Y) > (Z).
- 52. A device as claims in claim 50, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an analytical section and being in communication with the suction pressure generator.
- 53. A device as claimed in claim 51, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an

analytical section and being in communication with the suction pressure generator, the bypass channel branching from the drawing channel at a position between the division point and the opening.

- 54. A device as claimed in claim 50, wherein a gas-permeable and liquid-impermeable stopper is provided in the drawing channel between the suction pressure generator and the analytical section.
- 55. A device as claimed in claim 54, wherein the stopper is made from a hydrophobic porous material.
- 56. A device as claimed in claim 50 wherein the overall length of the device is 15 to 100 mm.
- 57. A device as claimed in claim 50, wherein the width of the device is 20 to 50 mm.
- 58. A device as claimed in claim 50, wherein the width of the device is 5 to 20 mm.
- 59. A device as claimed in claim 50, wherein the overall thickness of the device is 1 to 5 mm.
- 60. A device as claimed in claim 54 wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator.
- 61. A device as claimed in claim 50, wherein the device is designed to be discarded after a single use.
- 62. A device as claimed in claim 50, further comprising a bypass channel formed in the main body and branching from the drawing channel at a position between the

analytical section and the opening and in communication with the suction pressure generator.

- 63. A device as claimed in claim 62, wherein a liquid flow resistance in a first portion of the drawing channel between said analytical section and said suction pressure generator is greater than a liquid flow resistance in the bypass channel and a liquid flow resistance in a second portion of the drawing channel between said analytical section and a position at which said bypass channel branches.
- 64. A device as claimed in claim 50, wherein a positive pressure can be generated to return a sample withdrawn from the analytical section to the analytical section.
- 65. A device as claimed in claim 54, wherein a plurality of analytical sections are formed in the drawing channel, and the stopper is provided in the drawing channel between said suction pressure generator and the analytical section closest to the suction pressure generator.
- 66. A device as claimed in claim 50, wherein the opening has a shape enlarging toward the end.
- 67. A device as claimed in claim 50, wherein a liquid pooling portion is formed between the opening and t he drawing channel, and an air vent passage branches from a portion of the drawing channel between the liquid pooling portion and the analytical section, the end of the air vent passage opening to the outside.
- 68. A device a claims in claim 67, wherein the liquid flow resistance in the air vent passage is larger than the liquid flow resistance in the liquid pooling portion.
- 69. A device as claimed in claim 50, wherein the analytical section formed in the drawing channel serves as a reagent positioning section and a reagent reaction section.

- 70. A device as claimed in claim 50, wherein a reagent positioning section, a reagent reaction section and an analytical section are provided independently in certain positions in the drawing channel.
- 71. A device as claimed in claim 70, wherein a plurality of reagent positioning section are provided in certain positions in the drawing channel.
- 72. A device as claimed in claim 50, wherein a pair of electrodes comprising a working electrode and a counter electrode is provided in at least one analytical section.
- 73. A device as claimed in claim 40, wherein a concave portion with a cylindrical inner shape is formed in the main body as the chamber of the suction pressure generator and the flexible cover is disposed over the concave portion.
- 74. A device as claimed in claim 50, wherein a concave portion with a cylindrical inner shape is formed in the main body as the chamber of the suction pressure generator and the flexible cover is disposed over the concave portion.
- 75. A device as claimed in claim 28, wherein the analytical section is wider than the drawing channel and the drawing channel extends from the analytical section to the suction pressure generator.
- 76. A device as claimed in claim 50, wherein the analytical section is wider than the drawing channel and the drawing channel extends from the analytical section to the suction pressure generator.